REMARKS

Applicant affirms the election of the Group I claims 1-14. Claims 15-18 have been cancelled subject to their being placed in a divisional application at a later date.

We request approval of the drawing correction indicated in red on the enclosed Corrected Sheet. The identifier 58a has been added to Fig. 2. A Replacement Sheet showing this correction is also enclosed.

The enclosed amendments to the specification correct certain clerical errors included the ones noted by the Examiner.

Claim 1 has been amended to include means for measuring blood flow rate in response to the signals from the transmitter and to the receiver. Therefore, the claims conform to 35 USC 112.

Since no prior art has been cited against the claims, claims 1-14 should be allowed.

Please charge any additional fee occasioned by this paper to our Deposit Account No. 03-1237.

Respectfully submitted,

John F. McKenna
Reg. No. 20,912
CESARI AND MCKENNA, LLP
88 Black Falcon Avenue
Boston, MA 02210-2414
(617) 951-2500

Specification Amendment Schedule

[0001] The conventional method of measuring blood flow utilizes so-called thermodilution. An intravascular catheter carrying a temperature sensor such as a thermister or thermocouple is introduced into the pulmonary artery. Then saline is injected into the right atrium or ventricle to allow proper mixing of saline in the blood. Sometimes the saline is ~~a~~ at room temperature but more often it is at a lower temperature, e.g. 4°C, to increase the temperature difference from the patient's normal core temperature. The distance from the point of saline ~~rejection~~ injection to the sensor in the catheter is known more or less. Each time a saline bolus is injected, a clock is started to measure the time it takes for that bolus to flow to the sensor which thereupon emits a signal to stop the clock. The flow rate is determined by the dividing that fixed distance by the measured time interval.

[0010] The invention accordingly comprises the several steps at the relation of one or more of such steps with respect to each of the others, and the apparatus embodying the features of construction, combination of elements and arrangement of parts which are adapted to effect such steps, all ~~is~~ as exemplified in the following detailed description and the scope of the invention will be indicated in the claims.

[0011] Briefly, the present method utilizes microwave radiometry to measure intravascular blood flow. In accordance with the method, an intravascular catheter containing first and second axially spaced apart antennas is introduced into a patient's blood vessel. The catheter is connected to an ~~extracorporial~~ extracorporeal control unit which includes

a microwave transmitter capable of delivering microwave energy pulses having a first frequency to the first antenna to heat a small volume of blood adjacent to that antenna. The control unit also includes a microwave receiver connected to the second antenna and which operates at a second frequency so that when the volume of blood heated by the first antenna passes the second antenna, that thermal anomaly is picked up by the second antenna which thereupon delivers a corresponding signal to the receiver. In addition, the control unit has a processor which controls the operation of the transmitter and receiver and can compute the time interval between each transmitter pulse and the corresponding signal picked up by the receiver and divide that time interval into the known distance between the two antennas to provide the flow rate of the blood in the patient's vessel, which rate may be displayed on a display device in the control unit.

[0015] Referring to FIG. 1 of the drawing, the present apparatus comprises a flexible catheter shown generally at 10 for insertion into a blood vessel V. Catheter 10 is connected by coaxial cables 12a and 12b to a control unit 14. The catheter has a proximal end 10a to which cables 12a and 12b are connected by way of a fitting or connector 16 and a distal end or tip 10b. In a typical procedure, the catheter may be inserted into the patient through a standard introducer inserted in the patient's neck. The introducer is typically 8.5 French, ~~which~~ while the catheter may be 6 or 7 French. The catheter 10 goes from the jugular through the right side of the heart and then into the pulmonary artery.

[0016] As shown in FIG.1, catheter 10 incorporates coaxial inner and outer antennas 22_R and 22_T. The inner antenna 22_R comprises a coaxial cable consisting of an inner

conductor 24 and an outer conductor 26 separated by a dielectric layer 28, the outer conductor 26 being surrounded by a thin dielectric sleeve 32. The inner conductor 24 may be formed as a tube to accept a conventional guide wire (not shown) to help guide the catheter 10 into vessel V. The outer antenna 22_T consists of an inner conductor 34 and an outer conductor 36 separated by a dielectric layer 38. As seen in FIG. 1, the innermost conductor 24 projects beyond the next outer conductor 26 a distance L_1 and constitutes antenna 22_R. Also, the outermost conductor 36 is set back from the next inner conductor 34 a distance L_2 thus forming the outer antenna 22_T. The two antennas 22_R and 22_T are spaced apart axially a distance D, the conductors in that distance D basically constituting a short transmission line. Preferably, the inner coaxial cable constituting antenna 22_R is slidable relative to conductor 34 and the remaining outer conductors and fitting 16, enabling the adjustment of the distance D between the two antennas 22_R and 22_T.

[0018] Still referring to FIG. 1, the control unit 14 comprises a microwave transmitter 44 which operates under the control of a processor 46 in unit 44 to deliver microwave pulses at a fixed frequency F_T via cable 12a to antenna 22_T in catheter 10. Preferably, transmitter 24 is a solid state programmable transmitter which may operate at, say, 915MHz and may have a maximum power output of ~~0 to~~ 120 watts. Such a transmitter is available from Meridian Medical System, Inc. Acton, MA. That transmitted power causes antenna 22_T to emit electromagnetic radiation which heats the blood in the region L_2 surrounding that antenna.

[0019] The control unit 14 also includes a microwave receiver ~~46~~ 48 which receives signals F_R from antenna 22_R via cable 12b. Preferably, the radiometer is a Dicke-switch

radiometer of the type available from Meridian Medical System, Inc., Ayer, MA. It has a radiometer frequency in the range of 3.7 to 4.2 GHz, with a center frequency of 4.0 GHz. When a temperature anomaly is picked up from the region L_1 surrounding antenna 22_R, that signal F_R is detected by receiver 48 which delivers a corresponding output signal to processor 46. The processor thereupon computes the blood flow rate and sends a control signal to a display device 52, e.g. CRT, printer, plotter, etc., in unit 14 which displays that flow rate.

[0022] Refer now to FIG. 2 which shows the diplexer 42 in detail. As seen there, the diplexer includes a quarter-wave ($\underline{\lambda}_T/4$) stub to bring out the signal F_R from the inner antenna 22_R. The stub also provides a matched $90\underline{^\circ}$ bend to separate and bring out the signal F_T from the outer antenna 22_T so that the signal from the transmitter 44 is not coupled to the receiver ~~46~~ 48 and vice versa.

[0023] While it is known in the art to use a quarter-wave stub to support the center conductor of an antenna, the present diplexer has a tubular inner conductor 58 which receives the coaxial ~~table~~ cable 24-32 comprising the inner antenna 22_R that provides the signal F_R. That conductor 58 may be an extension of the antenna conductor 34. Surrounding and being insulated from conductor 58 is a coaxial outer conductor 62 which may be an extension of antenna conductor 36. The two diplexer conductors 58 and 62 are shorted by an end plate 64. Conductor 58 has a branch 58a which is brought out through a tubular branch 62a of conductor 62 to enable the delivery of the signal F_T to antenna 22_T. Preferably, the coaxial cable 24-32 is slidable to some extent along conductor 58 to vary the antenna distance D as described above.

[0027] It will thus be seen that the objects set forth above, among those made apparent from the preceding description, are efficiently attained. Also, certain changes may be made in carrying out the above method and the construction set forth without departing from the scope of the invention. For example, the positions of the two antennas 22_R and 22_T may be reversed in which case the diplexer would have a length ($\lambda_R/4$). Therefore, it is intended that all matter contained in the above description or shown in the accompanying drawing shall be interpreted as illustrative and not in a limiting sense.